

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
WESTERN DIVISION

KHALILAH JAMES , et al.,

Plaintiff,

Case No. 3:09 oe 40073

-vs-

MEMORANDUM OPINION

ORTHO-MCNEIL PHARMACEUTICAL, INC.,  
et al.,

Defendant.

KATZ, J.

Pending before the Court is a motion by Defendants for summary judgment on the issue of the warnings claim asserted by Plaintiff. Plaintiffs have filed a memorandum in opposition to that motion for partial summary judgment and Defendants have filed a reply memorandum. After a thorough review of all aspects of the failure-to-warn issue, it is clear to this Court that the Defendants' motion for summary judgment on that issue must be granted.

**BACKGROUND**

This matter involves a post-label change case in which several assertions and theories on liability are articulated in the complaint. Among those is a failure-to-warn theory; the Court agrees with Defendants that this theory is governed by both Louisiana law and the learned intermediary doctrine as applied in Louisiana.

Plaintiff, Ms. James, went to Dr. Kevin Plaisance for continuing assistance in birth control and other gynecological matters. Deposition testimony of Dr. Plaisance indicates clearly that he was aware of the level of estrogen exposure and the risks of clotting and pulmonary embolism associated with the Ortho Evra patch. Deposition testimony clearly reflects that the doctor had read the FDA approved package insert for that patch, as well as letters he received from the

manufacturer. Dr. Plaisance also testified on deposition that he told Ms. James about those risks before prescribing the patch for use by her, and further testified that he would prescribe the patch for her if she were to present herself to him “today” with the same medical history. He also testified that he still prescribes the patch to other patients.

Ms. James testified that she did not know about the risk of clotting from reading the label accompanying the Ortho Evra patch. Her testimony reflected that she never reads package inserts or patient information for prescription medications. She did acknowledge, at her deposition, that had she read the labeling she would have seen the numerous warnings regarding pulmonary embolism, but would have used the patch in any event because she relied on her doctor’s decision to prescribe it for her.

The Court incorporates by reference the Statement of Facts set forth in the memorandum accompanying Defendants’ motion for summary judgment (Doc. No. 15 at pp 2 - 8), and in Defendants’ reply brief (Doc. No. 18 at pp. 2 - 8).

## **DISCUSSION**

After a reading of the well-developed memoranda filed by the parties, it is clear to this Court that Dr. Plaisance testified as to his extensive knowledge about the risks associated with the Ortho Evra patch and describes those risks to patients, including Ms. James, before prescribing same. Further, it is clear that Ms. James did not read the warnings prior to commencing use of the patch, but that she relied upon her prescribing physician. During her deposition as reflected by the testimony, copies of which were contained in the memoranda filed by the parties, Ms. James has never denied that her physician advised her of the risk of pulmonary embolism associated with use of the patch. She further admitted that a co-worker had told her that clotting and pulmonary

embolism were associated with that patch. Thus, the issue before the Court is whether Ms. James failure-to-warn claims are barred by the learned intermediary doctrine.

#### **A. Summary Judgment Standard**

Summary judgment is appropriate where “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(c). The moving party bears the initial responsibility of “informing the district court of the basis for its motion, and identifying those portions of ‘the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,’ which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553, 91 L. Ed. 2d 265 (1986). The movant may meet this burden by demonstrating the absence of evidence supporting one or more essential elements of the non-movant’s claim. *Id.* at 323-25. Once the movant meets this burden, the opposing party “must set forth specific facts showing that there is a genuine issue for trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 106 S. Ct. 2505, 2541, 91 L. Ed. 2d 202 (1986) (*quoting* FED. R. CIV. P. 56(e)).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient “simply [to] show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986). Rather, Rule 56(e) “requires the nonmoving party to go beyond the pleadings” and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324, 106 S. Ct. at

2553; *see also Harris v. General Motors Corp.*, 201 F.3d 800, 802 (6th Cir. 2000). Summary judgment must be entered “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex*, 477 U.S. at 322, 106 S. Ct. at 2552.

“In considering a motion for summary judgment, the Court must view the facts and draw all reasonable inferences therefrom in a light most favorable to the nonmoving party.” *Williams v. Belknap*, 154 F. Supp. 2d 1069, 1071 (E.D. Mich. 2001) (citing *60 Ivy Street Corp. v. Alexander*, 822 F.2d 1432, 1435 (6th Cir. 1987)). However, ““at the summary judgment stage the judge’s function is not himself to weigh the evidence and determine the truth of the matter,”” *Wiley v. U.S.*, 20 F.3d 222, 227 (6th Cir. 1994) (quoting *Anderson*, 477 U.S. at 249); therefore, “[t]he Court is not required or permitted . . . to judge the evidence or make findings of fact.” *Williams*, 154 F. Supp. 2d at 1071. The purpose of summary judgment “is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried.” *Abercrombie & Fitch Stores, Inc. v. Am. Eagle Outfitters, Inc.*, 130 F. Supp. 2d 928, 930 (S.D. Ohio 1999). Ultimately, this Court must determine “whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” *Anderson*, 477 U.S. at 251-52; *see also Atchley v. RK Co.*, 224 F.3d 537, 539 (6th Cir. 2000).

### **B. Learned Intermediary Doctrine**

While the manufacturer of prescription medications has no duty to directly warn a patient regarding the potential risks associated with the use of the drug, the learned intermediary doctrine provides that where a prescribing physician stands between the manufacturer and the ultimate user, the manufacturer satisfies its duty to warn by giving adequate warnings to the prescribing

physician. *Mikell v. Hoffman-LaRoche, Inc.*, 649 So. 2d 75, 80 (La. Ct. App., 1994)(citing *Rhoto v. Ribando*, 504 So. 2d 1119, 1123 (La. Ct. App. 1987), *writ denied*, 506 So. 2d 1225 (La.1987)); *Stahl v. Novartis Pharmaceuticals Corp.*, 283, F.3d 254, 261 (5<sup>th</sup> Cir. 2002); *Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La. 1995)(citing *Willett v. Baxter Int'l., Inc.*, 929 F.2d 1094, 1098-99 (5<sup>th</sup> Cir. 1991) (applying Louisiana law)).

The Court agrees with Defendants that under Louisiana Products Liability Act, LA. REV. STAT. § 9:2800.57 (West 2005), a failure to warn claim requires Plaintiff to prove: 1) that the defendant failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician; and 2) that the failure to warn the physician was both a cause-in-fact and the proximate cause of the plaintiff's injury. *Zachary*, 884 F. Supp. At 1065; *Willett*, 929 F.2d at 1098. If plaintiff fails to make a sufficient showing to sustain either of these elements, summary judgment is appropriate. *Id.*

Under Louisiana law proof of proximate cause in this case with respect to failure to warn requires that "the plaintiff must show [] a proper warning would have changed the decision of the treating physician; but for the adequate warning, the treating physician would not have used or prescribed the product." *Zachary* at 1065; *Willett* at 1098. Clearly, Dr. Plaisance was aware of the risk of pulmonary embolism when he prescribed the Ortho Evra patch for Ms. James. (See Dep. testimony of Dr. Plaisance at pp. 18-19 of Doc. No. 15). He also testified that he counseled her regarding the greater risk of clotting with the use of the patch as compared to oral hormonal contraceptives. His testimony is replete with acknowledgment of both the knowledge of the risks and that he advised Ms. James of those risks. Ms. James acknowledges that she was so advised. The deposition testimony of both the Dr. Plaisance and Ms. James as excerpted in the reply

memorandum of Defendants clearly supports these conclusions. Because Louisiana law does not recognize a direct-to-consumer advertising exception to the learned intermediary doctrine, that exception is not available to Plaintiffs.

## **CONCLUSION**

Because Plaintiffs have not come forth with any evidentiary material to support their failure to warn claim, the motion for summary judgment as to that claim must be granted. The extensive deposition testimony of both Ms. James and Dr. Plaisance as reviewed by this Court reflects no other legal course would be appropriate.

IT IS SO ORDERED.

s/ David A. Katz  
DAVID A. KATZ  
U. S. DISTRICT JUDGE